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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,418	04/26/2006	Shirou Sawa	2006_0177A	7556

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
06/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/568,418	SAWA ET AL.
	Examiner	Art Unit
	GIGI HUANG	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed October 29, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1, 10-11 have been amended.

   b. Claim 5-7, 9 has been cancelled.

2. Claims 1, 3, 10-11 are pending in the case.

3. Claims 1, 3, 10-11 are present for examination.

4. All grounds not addressed in the action are withdrawn or moot as a result of amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. (U.S. Pat. No. 4910225) in view of Leike et al. (Effects of Compound Taurine Eye Drops on Ocular Inflammation in Rabbits).

Ogawa teaches a method of treating inflammatory eye disease with an ophthalmic composition comprised of a benzoylphenylacetic acid or its salt or the

hydrate, buffers, additional pharmaceutical actives (e.g. anti-inflammatories), and excipients (e.g. an isotonizing agent, a preservative, a chelating agent).

Specific exemplified benzoylphenylacetic acid compound of sodium 3-(4-bromobenzoyl) 2-aminophenylacetate/monohydrate is the instant claimed compound (bromfenac).

The concentration of the benzoylphenylacetic acid compound is about 0.001% to about 10%, preferably in the range of 0.01 to about 5%. The composition can be in the form of a solution (aqueous and non-aqueous) and be administered as eye drops, ointments and any other known compositions for topical administration to the eye. The eye drops are to be administered one to several drops per dose in a frequency of once to four times a day according to the clinical condition. The dosage may be adjusted according to symptoms.

The examples teach compositions comprising the bromfenac at 0.1% (sodium 3-(4-bromobenzoyl) 2-aminophenylacetate/monohydrate) with excipients including buffers such as boric acid-borax (sodium borate) and sodium monohydrogen phosphate-sodium dihydrogen phosphate at about 1.0%w/v(Experimental Example 3-4),about 1.5%w/v (Experimental Example 5-6), and in ophthalmic solutions at certain points ranging from about 0.2%w/v to 2.25%w/v (about 0.2%w/v-Example 9, about 0.7%w/v-Example 7, about 1.5%w/v-Example 8, 2.25%w/v-Example 6). The recitation of the maintenance of bromfenac in the vitreous humor is a recitation of intended effect which is intrinsically met when the components present in the composition (e.g. bromfenac, the organic amine) and the mode of administration are met as the results are the same

as any component or step that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope (Abstract, Col. 1, lines 33-38, 60-68, Col. 2, lines 1-36, 45-68, Col. 3, lines 30-54, Col. 4, lines 20-68, Col.5, lines 1-15-23, Col.6, lines 20-48, 53-68, Col.7, lines 1-68, Col8, lines 1-20, 25-68, Col.9, Example 1-2, Col.10, Example 6-7).

Ogawa et al. does not expressly teach the incorporation of taurine (aminoethylsulfonic acid) in the composition.

Leike et al. teaches that taurine is an effective anti-inflammatory for the eye.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate taurine, as suggested by Leike, and produce the instant invention; as it is obvious to combine two anti-inflammatories (bromfenac and taurine) each of which is taught by prior art to be useful for same purpose (same field of endeavor) in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.

One of ordinary skill in the art would have been motivated to do this as it is routine in the art to have combine of drugs for the same purpose to provide a more effective composition to treat the condition desired. Ogawa teaches explicitly, the incorporation of other active agents (Col. 4, lines 16-20).

6. Claims 1, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al. (U.S. Pat. No. 4910225) in view of Leike et al. (Effects of Compound Taurine Eye Drops on Ocular Inflammation in Rabbits) as applied to claims 1,3, 11 above, further in view of Kato (U.S. Pat. 5945121).

The teachings of Ogawa in view of Leike are addressed above.

Ogawa in view of Leike does not expressly teach the amount of taurine for the composition.

Kato et al. teaches that taurine known to be ophthalmically useful in the range of 0.5 to 3.0% by weight for inflammatory conditions of the eye (e.g. dry eye, Col. 1, lines 38-43).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate taurine at 0.5-3.0%, as suggested by Kato et al., and produce the instant invention; as it is obvious to incorporate taurine in its known ophthalmically useful range (0.5-3.0%), particularly as the range is useful for a known inflammatory condition (e.g. dry eye) with a reasonable expectation of success; and is desirable for the skilled artisan to use a range that is already known to be safe and therapeutically useful for the same mode of administration for the same active.

Response to Arguments

7. Applicant's arguments with respect to the art have been considered but are moot in view of the new grounds of rejection.

Applicant's arguments filed 10/29/2010 in regards to unexpected results have been fully considered but they are not persuasive. Applicant's arguments to the inhibition rate of Formulation 4 verses that of Formulation 5 and 6 as begin superior and unexpected is fully considered but not persuasive. First the inhibition rate cited in Table 5 is not fully clear on what is being indicated as Formulation 4 (no taurine) while being 0.3% states n=6, Formulation 5 (0.5% taurine) has an inhibition rate of 25.5% with n=7, Formulation 6 (1.0% taurine) has an inhibition rate of 73.9% with n=10; but there is no indication in the example as to what "n" is. Is it a statistical measure? If so what is the measure? Average? SD? Is it the number of samples? If so, what was the number of total samples to allow for the percentage with the improvement? It does not allow one to ascertain the significance of the test.

Additionally, the test is not commensurate in scope with the claims as written. The test is directed to taurine only, wherein the claims are directed to taurine and aminomethylsulfonic acid. Also the test is directed for the data points of taurine at 0.5% and 1.0%, yielding a range for 0.5-1.0%w/v which is not commensurate in scope for the dependent claimed range of 0.05-5.0%w/v.

Lastly as seen with Ogawa in view of Leike, taurine is anti-inflammatory wherein the results could be the result of the additive effects of combining the two anti-inflammatories. There is no evidence presented that it isn't an additive effect which

would be expected, verses a synergistic effect which would not be expected; nor that this effect is specific to taurine verses other amines to be deemed unexpected.

Accordingly, the rejection stands.

Conclusion

8. Claims 1, 3, 10-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:00AM-6:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENIVASAN PADMANABHAN can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1627
/Zohreh A Fay/
Primary Examiner, Art Unit 1627